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(54) **RADIATION ACTIVATED GELS THAT RELEASE FLUIDS AND ASSEMBLIES CONTAINING THE SAME**

(57) Gels that release fluid and assemblies containing the same.

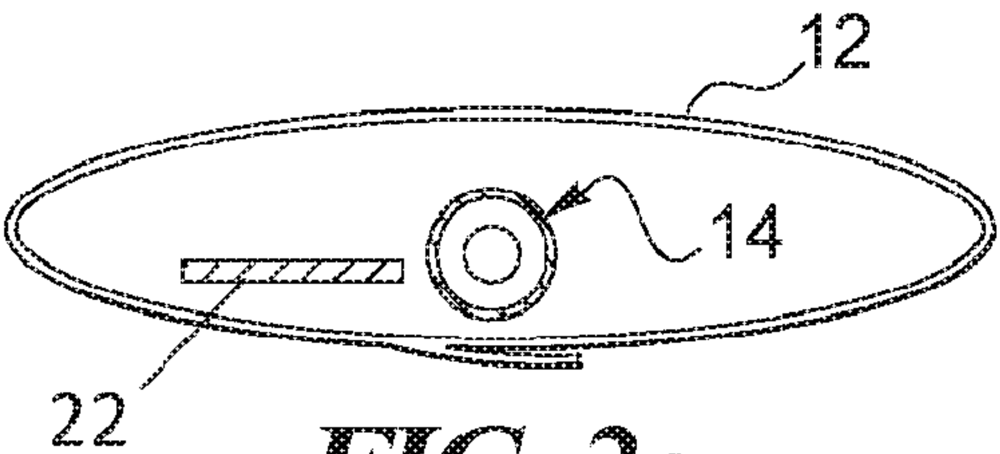

FIG. 2c

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Description

Related Application

[0001] The present application claims the benefit and priority of U.S. Provisional Patent Application No. 62/461,730, filed February 21, 2017, and U.S. Provisional Patent Application No. 62/545,730, filed August 15, 2017, both of which are hereby incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure generally relates to hydration gels that release fluid for hydrating or wetting materials, such as hydrophilic materials, and more particularly, to radiation activated hydration gels that contain a fluid which is released from a gel upon exposing the gel to radiation. The present disclosure also generally relates to assemblies that include products having a material to be wetted or hydrated or a material to be stored in a wet state and a fluid releasing hydrogel. The present disclosure also generally relates to methods for radiation sterilization of materials, such as hydrophilic materials.

BACKGROUND

[0003] One method of sterilization includes exposing an item or product to radiation to kill the microbes and sterilize the item/product. There are items/products wherein the conditions under which the radiation sterilization occurs can cause damage to the items/products. For example, there are certain items that are required to be radiation sterilized in dry or substantially dry conditions. If such items are radiation sterilized in a wet or hydrated condition, the exposure to radiation may lessen one or more qualities of the item or will damage the item. For example, some types of hydrophilic materials may become damaged by exposure to sterilizing radiation while the hydrophilic materials are in a hydrated state.

[0004] It is known to coat medical devices, such as urinary catheters, with a hydrophilic coating. When the hydrophilic coating is wetted or hydrated with a wetting fluid, such as water, it becomes extremely lubricous which eases introduction of the device into the body and aids in reducing pain and discomfort associated with such introduction.

[0005] In some applications, the hydrophilically coated medical device is provided in a "dry" state wherein the user is required to wet the hydrophilic coating with a wetting fluid immediately prior to insertion into the body. In other applications, it is desirable to provide a hydrophilically coated medical device that is in a ready-to-use condition right out of the package. In the field of urinary catheters, a hydrophilically coated catheter may be provided in a catheter package wherein the catheter is stored in the package in contact with water so that the hydrophilic coating is wetted within the package and the catheter is ready for use right out of the package.

[0006] For various reasons, including but not limited to efficiency, effectiveness and cost, it is desirable to radiation sterilize packaged medical device assemblies. In some instances, the hydrophilically coated medical device and water are placed in the package and the package is sealed. After the package is sealed, the package having the hydrophilically coated medical device and water therein is exposed to radiation, such as gamma or E-Beam radiation, to sterilize the medical device. It has been found, however, that sterilization of hydrophilic coatings in the hydrated state or while in contact with a wetting fluid can result in degradation of the coating or excessive crosslinking of the coating which can lead to an increase of coefficient of friction (decrease in lubricity) of the coating and/or cause instability of coating which may result in the coating undesirably detaching from the medical device prior to or during use.

[0007] Therefore, there remains a need for sterilized ready-to-use hydrophilic medical devices and methods of sterilizing hydrophilic medical devices.

SUMMARY

[0008] There are several aspects of the present subject matter which may be embodied separately or together in the devices and systems described and claimed below. These aspects may be employed alone or in combination with other aspects of the subject matter described herein, and the description of these aspects together is not intended to preclude the use of these aspects separately or the claiming of such aspects separately or in different combinations as set forth in the claims appended hereto.

[0009] In one aspect, an assembly includes a device and a radiation activated fluid releasing gel containing a fluid, such as liquid. The liquid may be, for example, liquid water or a solution containing water. In one embodiment, the fluid is a hydration fluid that hydrates a material of the device. Prior to exposing the assembly to sterilizing radiation, the fluid releasing gel retains the fluid and prevents or substantially prevents the fluid from contacting the device. As such, prior to radiation, the device is in a dry or substantially dry state. When the device includes a hydrophilic material, the hydrophilic material may be in non-hydrated or non-fully hydrated state. Because of this, the device may be irradiated in a dry state and/or the irradiation may begin while the device is not in contact with the fluid contained in fluid releasing gel. Upon exposure to radiation, the gel releases the fluid, which contacts the device, thereby resulting in a sterilized device.

[0010] In another aspect, a method of sterilizing a device including placing a device and a gel containing a fluid within a package, and exposing the device and gel to sterilizing radiation, wherein the gel is activated or triggered to release the fluid, such as liquid water or a solution containing water, upon exposure to the radiation.

BRIEF DESCRIPTION OF FIGURES

[0011]

Fig. 1 is a plan view of a catheter assembly in accordance with the present disclosure;
Fig. 2a is a cross-sectional view of one embodiment of the catheter assembly of Fig. 1 taken along line 2-2;
Fig. 2b is a cross-sectional view of another embodiment of the catheter assembly of Fig. 1 taken along line 2-2;
Fig. 2c is a cross-sectional view of another embodiment of the catheter assembly of Fig. 1 taken along line 2-2; and
Fig. 2d is a cross-sectional view of another embodiment of the catheter assembly of Fig. 1 taken along line 2-2.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

[0012] The embodiments disclosed herein are for the purpose of providing a description of the present subject matter, and it is understood that the subject matter may be embodied in various other forms and combinations not shown in detail. Therefore, specific embodiments and features disclosed herein are not to be interpreted as limiting the subject matter as defined in the accompanying claims.

[0013] The present disclosure discloses gels that are activated to release fluids and assemblies that include the same. The fluids may be, for example, liquid water or a solution containing liquid water. The gels may be radiation activated in that when the gel is exposed to radiation, such as sterilizing E-beam or gamma radiation, the gel degrades or breaks down, thereby releasing fluid. Such gels may be used in any assembly that requires the liquid fluid to remain within the gel prior to being exposed to radiation. For example, hydration gels may be used in an assembly that includes a device and a hydration gel wherein the hydration gel retains fluids and keeps the fluid from contacting the device until the hydration gel is activated or broken down by exposure to radiation to release the fluid.

[0014] The gels disclosed herein may be used in any field or industry, e.g. consumer products, medical products, industrial products, food products, textiles etc. The gels may be employed in any package or situation that requires active hydration of an item after radiation. In one example, the fluid releasing gels may be used with any item that expands in dimensions upon contact with a liquid. For example, a sponge may be in a compact configuration when in a dry state and in an expanded configuration when in a wet state. The sponge may be packaged with a fluid releasing gel in the dry state. After being exposed to radiation, the gel releases fluid that wets the sponge, thereby expanding the sponge.

[0015] In another example, the gels may be used in medical device assemblies. The medical device may include any natural or synthetic material wherein the material is required to be separated from the fluid of the gel until the gel releases the fluid. Such materials may include polymers, metals, organic material, tissue, etc. In one embodiment, such gels may be used to hydrate hydrophilic materials during and/or after exposure to sterilizing radiation. Such medical devices may include any medical device that utilizes a lubricious hydrophilic material, including but not limited to, urinary catheters, endoscopes, anal catheters, vascular catheters, etc. The lubricious hydrophilic material may be a hydrophilic coating on the device.

[0016] In one embodiment, the assembly includes a hydrophilically coated medical device (such as a urinary catheter or anal catheter) and a hydration gel containing a fluid, such as a hydration fluid, which may be liquid water or a solution containing water. Prior to releasing the fluid, the hydration gel retains the fluid, thereby preventing or substantially preventing the fluid from hydrating the hydrophilic coating. That is, the hydrophilic coating is in a dry (non-hydrated) or a non-fully hydrated state. The medical assembly is then exposed to sterilizing radiation with the hydrophilic coating in the dry or non-fully hydrated state. Upon exposure radiation, the hydration gel releases the fluid. The released fluid hydrates the hydrophilic coating on the medical device, rending the hydrophilic coating lubricous and ready for use, and resulting in a sterilized ready-to-use medical device. In hydrating the hydrophilic coating, the fluid may be in direct liquid contact with the hydrophilic coating and/or the released liquid fluid may produce a vapor that hydrates the hydrophilic coating.

[0017] The hydration gel may be any fluid containing gel that is activated to release the fluid upon being exposed to radiation. In one embodiment, when the gel is exposed to radiation, the gel degrades or breaks down, thereby releasing the fluid. For example, upon exposure to radiation, the viscosity of the gel may be lowered or the gel may liquefy, thereby releasing the fluid.

[0018] In one embodiment, the gels may include a polymeric mixture and an amount of fluid. For example, the gel may be a water soluble polymer based hydrogel, such as a saccharide based hydrogel. In one embodiment, the hydrogel may be a polysaccharide based gel which includes a polysaccharide and a concentration of fluid. The gel may be, for example, various hydrocolloids that form a gel in the presence of water. Such hydrocolloids include but are not limited to gellan gum, high acyl gellan gum, low acyl gellan gum, xanthan gum, deacetylated xanthan gum, depyruvated xanthan gum, galactomannans, glucomannans, and combinations thereof and a concentration of fluid. In one embodiment, the gel is a thermoreversible gel that is radiation degradable, such as a xanthan gum based gel. The concentration of the polymeric mixture of the gel may be between about 60 wt% and about 0.1 wt%. In one embodiment, the concentration of the polymeric mixture may be between about 0.1 wt% and about 5 wt% or between about 1 wt% and about 2 wt%, or between about 1.25 wt% and about 1.75 wt%.

[0019] The concentration of the fluid in the gel may be between about 40 wt% and about 99.9 wt%. In one embodiment, the concentration of the fluid in the gel is about 98 wt% with difference being the polymeric mixture and optional additives. In one embodiment, the hydrogel may include a polymeric mixture in an amount of between about 1 wt% and about 2 wt% and fluid in an amount of between about 98 wt % and about 99 wt%.

[0020] The fluid may be any liquid fluid. In one embodiment, the fluid is a liquid fluid that hydrates the hydrophilic coating by direct liquid contact and/or by donating a vapor. In one embodiment, the fluid may include water or a solution containing water. The fluid may also be a saline solution. The fluid and/or the gel may also include additives, which may be functional components of the fluid, the gel and/or both. Such additives may include but are not limited to, ionic compounds, plasticizers, alcohols, osmolality increasing agent, antibiotics, etc. For example, the ionic compounds may be those that include sodium, potassium, calcium and/or magnesium. Furthermore, the additives may be outside of and adjacent to the gel wherein the additives mix with the fluid when the fluid is released from the gel. In another embodiment, the assembly may include two or more gels wherein each gel has different components, such as different fluids, concentration of fluids and/or additives.

[0021] The hydrogel may include one or more additives which serve as hydrogel stabilizing or strengthening agents, such as simple polyols (such as glycerol), polyethers (such as Polyethylene glycol) and/or carboxylic acid (such as citric acid, polycarboxylic acid or salts thereof). For example, the additives may be one or more of glycerol, Polyethylene glycol, Xylotol, sodium citrate, tartaric acid, oxalic acid, poly(acrylic acid and poly(acrylic acid) salt (such as sodium). The polyols and polyethers may have molecular weights between about 100 Mw and about 600 Mw. In one embodiment, the hydrogel may include glycerol in a concentration of less than about 5 wt% or in less than about 2 wt%. For example, the glycerol concentration may be between about 0.1 wt% and about 5 wt%, or between about 0.5 wt% and about 2 wt%, or between about 0.1 wt% and about 1 wt% or between about 0.25 wt% and about 0.5 wt%. In another embodiment, the hydrogel may include polyethylene glycol in a concentration a concentration of less than about 5 wt% or in less than about 2 wt%. In addition to glycerol and polyethylene, or in the alternative to these, the hydrogel may include citric acid. The citric acid may be in the amount between about 0.01 wt% and about 2 wt%, or between about 0.01 wt% and about 0.5 wt% or between about 0.05 wt% and about 0.1 wt%.

[0022] It is desirable for the amount of stabilizing agents to be sufficient to stabilize the gel but to also allow the hydration gel to breakdown or release the fluid upon exposure to radiation, such as sterilizing gamma or E-beam radiation. If the amount of stabilizing agent included in the hydration gel is too great, the hydration gel may not sufficiently breakdown or release the fluid.

[0023] Some fluids for hydrating hydrophilic catheters have been known to cause stains when the fluid is spilled or otherwise comes into contact with clothing. While some hydrophilic catheter packages are designed to reduce the risk of fluid spillage, accidents still occur, which can leave unsightly or embarrassing stains on the user's clothing. Surprisingly, with the addition of additives to the hydration gels, the fluid released from the hydration gel does not stain or results in reduced staining of clothes.

[0024] The gels may include an anti-staining agent(s) that may mask or act as a clarifying agent. Such anti-staining agents may include the same simple polyols (such as glycerol), polyethers (such as polyethylene glycol) and/or carboxylic acid (such as citric acid) that also act as stabilizing/strengthening agents. The anti-staining agents can result in no staining, reduced staining and/or the formation of a transparent film or residue on the clothing. In one embodiment, a hydration gel includes a polymeric composition, such as gellan gum, a stabilizing and/or anti-staining agent such as (glycerol, PEG and/or citric acid). For example, the hydration gel may include between about 1 wt% and about 2 wt% of the polymeric composition, between about 0.1 wt% and about 2 wt% stabilizing and/or anti-staining agents (which may be the same of different agents), and between about 96 wt% to about 98.9 wt% fluid (such as water or saline). In another embodiment, the anti-staining agents may be contained in the above concentrations in a wetting fluid for wetting or hydrating a hydrophilic catheter. Such anti-staining wetting fluid may be contained in a gel or it be placed directly into a package without the use of gel. For example, such anti-staining wetting fluid may be placed directly into the package with a hydrophilic catheter wherein the wetting fluid is in direct contact with the catheter or at some point in time brought into direct contact with the catheter.

[0025] One embodiment of a medical device assembly includes a package containing a hydrophilically coated medical device (such as a urinary or anal catheter) and a gel containing a fluid wherein the gel releases the fluid to hydrate the hydrophilically coating of the medical device in the package. The gel may be a radiation activated hydration gel that releases the fluid upon exposure to radiation, such as gamma or E-beam sterilizing radiation. After, sterilization, the medical device within the package is sterilized and in a ready-to-use hydrated state. With the medical device in a ready-to-use state, the package is distributed to the user wherein the medical device is ready to use when the package is opened by the user.

[0026] A gel and the device may be configured within the package in any variety of manners. For example, the gel may serve as a reservoir of fluid that retains the fluid until the gel releases the fluid, by for example, degradation of the gel from exposure to radiation. The gel may or may not be in contact with the device prior to release of the fluid. The device may be, for example, a medical device. In one embodiment, the gel at least partially covers or is partially spread over the device. Alternatively, the gel may substantially cover or be substantially spread over the device. For example, when the device includes a hydrophilic coating, the gel may at least partially or substantially cover of at least the hydrophilic coating of the medical device. In another embodiment, the gel and the device may be unconstrained relative to one another within the package, wherein the gel and device are free to move about relative to one another. In yet another embodiment, the gel may be confined within a section of the package or in isolation relative to the device. For example, the gel may be separated from the device by a gas permeable barrier, which in one embodiment also may be a liquid impermeable barrier. In such an embodiment, when the liquid fluid is released, the liquid fluid provides a vapor that permeates through the barrier and hydrates the hydrophilic coating. Another embodiment may include placing the gel and hydrophilic catheter, such as a urinary or anal catheter, within a liquid impermeable barrier such that it can provide more efficient direct hydration of the hydrophilic material of the catheter.

[0027] In one method of sterilizing a medical device containing a hydrophilic material, such as a hydrophilically coated urinary or anal catheter, the medical device and a hydration gel are placed within a package. The package may or may not be sealed. The hydration gel may be placed in the package in any suitable manner. For example, during formation of the hydration gel, the gel may be cast into a desired shape which is placed in the package. The hydration gel may be cut into desired shapes. For instance, during formation of the gel, the gel may be cast on a plate and then cut into rectangles that are placed in the package. The hydration gel may also be placed in an injection member, such as a syringe or dispenser with dosing capability wherein the gel is injected into the package. The hydrogel may be cast or impregnated into a fabric or wicking material.

[0028] Prior to sterilization, the gel retains the hydration fluid so that the hydration fluid does not hydrate or substantially hydrate the hydrophilic material of the medical device. The package is then exposed to sterilizing radiation wherein the sterilizing radiation activates the gel to release the hydration fluid. For example, the hydration gel degrades upon exposure to the radiation and releases the hydration fluid. The hydration fluid then hydrates the hydrophilic material, thereby resulting in a sterilized ready to use medical product.

[0029] Referring to Fig. 1, the assembly 10, which may be a urinary or anal catheter assembly, includes an outer package 12, which may be a gas impermeable package, such as a foil package. The package 12 may define a sealed cavity that contains a device 14. The device 14, which may be a urinary or anal catheter, may be a hydrophilic catheter that may be made of a hydrophilic material or includes a hydrophilic coating on the outer surface of the shaft of the catheter. A wick 16 may also be included in the cavity of the package 12 (Fig. 2a). The wick 16 may, optionally, extend along at least a length of the device 14. As illustrated in Fig. 2a, the wick 16 may, optionally, be covered by a gas permeable, liquid impermeable barrier 18. The barrier 18 may be attached about its periphery to an inner wall of the package 12 to define a space/compartment containing the wick 16. Additionally, when the device 14 is a catheter, the shaft of catheter may be surrounded by a gas permeable non-touch sleeve 20 or may include a catheter gripping device. The wick 16 may be covered or impregnated with a gel that retains fluid. In this embodiment, after the gel releases the fluid (e.g., after exposure to sterilizing radiation), the fluid donates a gas, such as water vapor, that passes through the gas permeable, liquid impermeable barrier 18 and the no-touch sleeve 20, if these features are present. The gas hydrates the material of the device 14 so that it is ready to use. For example, water vapor hydrates the hydrophilic material of the catheter.

[0030] Figs. 2b-2d illustrate other exemplary embodiments of the present disclosure. In Fig. 2b, the gel 22 is located in the space/compartment defined between the gas permeable, liquid impermeable barrier 18 and the internal wall of the package 12. In this embodiment, there is no wicking member and/or a no-touch sleeve, but these features could be include if desired. The gel may be injected into the space between the barrier 18 and wall of the package 12 or the gel may be a shaped piece that is placed into this space. In Fig. 2c, the gel 22 is located in the same cavity or compartment as the device 14, such as a urinary or anal catheter, such that when the gel 22 releases the liquid hydration fluid, the liquid directly contacts the hydrophilic material of the device 14 to hydrate such material. The gel may be injected into the package 12 by an injection device or the gel may be a shaped piece that is placed in the package 12. In Fig. 2d, the gel 22 is contained within a no touch sleeve surrounding at least a portion of the device 14. In one embodiment, the device may be a urinary or anal catheter having a shaft including hydrophilic material. After the gel 22 releases the liquid hydration fluid, the liquid and the device 14 are both contained within the sleeve 20a and the liquid directly contacts the material of the device 14 to hydrate the material of the device. For example, the liquid may directly contact the hydrophilic material of a catheter within the sleeve. The sleeve 20a may be a gas and liquid impermeable sleeve that contains the liquid within the sleeve.

EXAMPLES

Example I - Gel Formation

[0031] In the below described examples, a hydrogel was formed by heating water to 75 °C and then dissolving an amount of gellan gum (Kelcogel® CG-LA supplied by CP Kelco and polyethylene glycol) in the water. If an additive(s) (such as glycerol, citric acid, polyethylene glycol) was being incorporated into the hydrogel, the additive(s) was added after the gellan gum was dissolved. The mixture was allowed to cool, thereby forming a fluid releasing hydrogel.

Example II

[0032] A hydrogel including 2 wt% gellan gum and 98 wt% water was formed in the manner described above in Example I. The catheters having a hydrophilic coating on the catheter shaft along with the hydrogel were individually packaged in a vapor hydrating, gas impermeable package (such as the package of Hollister's commercial VaPro® product). In particular, such packages included a sealed gas impermeable outer foil pouch which contains the hydrophilic catheter within a cavity of the pouch. The packages also include a vapor permeable, liquid impermeable microporous barrier that is sealed, about its periphery, to an interior surface of the foil pouch. The microporous barrier was made of polyethylene impregnated with calcium carbonate. A wicking fabric was located and contained between the microporous barrier and the interior surface of the package.

[0033] During packaging of the catheters of Example II, the hydration gel was spread on the wicking fabric, which was then placed between the microporous barrier and interior surface of the pouch. The microporous barrier was then sealed to the interior surface of the pouch. The hydrophilic catheter have a no-touch gas permeable sleeve surrounding the catheter shaft (similar to that of Hollister's VaPro® commercial product) was placed into the cavity of the foil pouch and the pouch was sealed. The packages were then exposed to gamma radiation at a dose of between about 25 kGy and about 45 kGy. The packages were stored for five days.

[0034] After storage, the packages were opened, the catheters were removed and the coefficients of friction of the catheters were measured. In particular, the the initial, abraded and ten minute dry-out coefficients of friction (CoFs) of each of the catheters was measured with the hydrophilic coating in a hydrated state.

[0035] The CoF measurements are an indicator of lubricity and were measured using a Harland Friction Tester Model FTS5500. The CoFs of the catheters were determined by inserting a mandrel into 127 mm section of the coated catheter tube. The tube was then clamped between two pieces of silicone rubber at 100g load wherein the silicone rubber had a shore hardness of 60A. The catheter tube with the mandrel inserted therein was pulled through the two pieces of silicone rubber at a speed of 10 mm/s. The force required to pull about 80 mm of the catheter tube through the two pieces of silicone rubber was measured. The CoF value was calculated from the ratio of recorded to applied loads (i.e., the recorded load divided by the applied load) when steady state was reached. The CoF of each catheter was measured immediately after removal from the package ("initial"), immediately after being abraded ("abraded") and immediately after a ten-minute dry-out time ("dry-out").

[0036] In measuring the abraded CoFs, the catheter, with the hydrophilic coating in a hydrated state, was cycled back and forth 25 times through a hole in a 1 mm thick, silicone pad having a shore hardness of 60A. The hole about 90% of the diameter than the outer diameter of the catheter tube and the abrasion took place under water. Abrading the catheter in this fashion is designed to remove any portions of the coating that is not well adhered to the tubes. After abrasion, the CoF was measured as described above.

[0037] In measuring the ten minute dry-out time CoF, the catheter was removed from the package and was placed in an atmosphere having a temperature of 23°C and a relative humidity of 50% for 10 minutes before measuring the CoF as described above.

[0038] Dye uptake tests also were conducted on the catheters to assess the level of adhesion/non-adhesion between the hydrophilic coatings and catheters. After the CoFs of the "abraded" and "dry out" catheters were measured, the catheters were dehydrated. The dehydrated catheters were then immersed in a water soluble red dye for 2 minutes. The catheters were then visually inspected to determine if the dye had been uniformly taken up throughout the coating or if sections of the coated portion of the catheter were dye-free. A uniform dye uptake throughout the coated portion of the catheter indicates that the hydrophilic coating has good adhesion to the catheter and is indicated as "pass" in the result tables below. If the coated portion of the catheter has undyed sections, this is an indication that the hydrophilic coating or sections thereof have significantly thinned and/or separated from the catheter due to lack of adhesion to the catheter.

[0039] Table 1 lists the initial and abraded CoF measurements and the results of the dye test of the abraded catheter samples.

Table 1

Sample	Initial COF	Abrasion COF	Abraded Dye Test
2-1	0.016	0.011	Pass
2-2	0.020	0.018	Pass
2-3	0.017	0.014	Pass
2-4	0.018	0.006	Pass
2-5	0.019	0.010	Pass
2-6	0.016	0.017	Pass
2-7	0.014	0.008	Pass
2-8	0.011	0.009	Pass
Average	0.016	0.011	
Std. Dev.	0.003	0.004	

[0040] Table 2 lists the dry out CoF measurements and the results of the dye test after the dry out CoFs were measured for the catheter samples.

Table 2

Sample	10Min Dry Out COF	Dry Out Sample Dye Test
2-9	0.025	Pass
2-10	0.026	Pass
2-11	0.028	Pass
2-12	0.028	Pass
2-13	0.025	Pass
2-14	0.026	Pass
2-15	0.029	Pass
2-16	0.027	Pass
Average	0.027	
Std. Dev.	0.002	

Example III

[0041] A hydrogel including 2 wt% gellan gum and 98 wt% water was formed in the manner described above in Example I. The catheters having a hydrophilic coating on the catheter shaft were individually packaged with the hydrogel spread on the fabric of a vapor hydrating, gas impermeable package, as described above in Example II. In this example, the catheter did not include a no-touch sleeve. The packages were exposed to gamma radiation and stored, as described above in Example II. The initial, abraded and dry-out CoFs were measured and dye uptake tests were conduct in the same manner as described in Example II.

[0042] Table 3 lists the initial and abraded CoF measurements and the results of the dye test of the abraded catheter samples.

Table 3

Sample	Initial COF	Abrasion COF	Abraded Dye test
3-1	0.015	0.010	Pass
3-2	0.021	0.070	Pass
3-3	0.020	0.010	Pass
3-4	0.014	0.027	Pass
3-5	0.017	0.013	Pass
3-6	0.037	0.010	Pass
3-7	0.018	0.023	Pass
3-8	0.011	0.006	Pass
Average	0.019	0.021	
Std. Dev.	0.008	0.021	

[0043] Table 4 lists the dry out CoF measurements and the results of the dye test after the dry out CoFs were measured for the catheter samples.

Table 4

Sample	10Min Dry Out COF	Dry Out Sample Dye Test
3-9	0.025	Pass
3-10	0.010	Pass
3-11	0.026	Pass
3-12	0.011	Pass
3-13	0.026	Pass
3-14	0.023	Pass
3-15	0.024	Pass
3-16	0.027	Pass
Average	0.022	
Std. Dev.	0.007	

Example IV

[0044] A hydrogel including 2 wt% gellan gum and 98 wt% water was formed in the manner described above in Example I. The catheters having a hydrophilic coating on the catheter shaft and a no-touch sleeve surrounding the catheter shaft were individually packaged with the hydrogel in a vapor hydrating, gas impermeable package, as described above in Example II, except that the package did not contain a wicking fabric in the space between the microporous barrier and the interior surface of the pouch. Instead, the hydrogel was placed in a syringe and injected between the microporous barrier and the interior surface of the pouch. The packages were exposed to gamma radiation and stored, as described above in Example II. The initial, abraded and dry-out CoFs were measured and dye uptake tests were conduct in the same manner as described in Example II.

[0045] Table 5 lists the initial and abraded CoF measurements and the results of the dye test of the abraded catheter samples.

Table 5

Sample	Initial COF	Abrasion COF	Abraded Dye test
4-1	0.016	0.013	Pass
4-2	0.017	0.018	Pass
4-3	0.017	0.007	Pass
4-4	0.022	0.007	Pass
4-5	0.016	0.008	Pass
4-6	0.010	0.007	Pass
4-7	0.012	0.016	Pass
4-8	/	/	Pass
Average	0.016	0.011	
Std. Dev.	0.004	0.005	

[0046] Table 6 lists the dry out CoF measurements and the results of the dye test after the dry out CoFs were measured for the catheter samples.

Table 6

Sample	10Min Dry Out COF	Dried Dye test
4-9	0.027	Pass
4-10	0.029	Pass
4-11	0.028	Pass
4-12	0.025	Pass
4-13	0.024	Pass
4-14	0.025	Pass
4-15	0.027	Pass
4-16	/	Pass
Average	0.026	
Std. Dev.	0.002	

Example V

[0047] A hydrogel including 2 wt% gellan gum and 98 wt% water was formed in the manner described above in Example I. The catheters having a hydrophilic coating on the catheter shaft were individually packaged with the hydrogel in a vapor hydrating, gas impermeable package, as described above in Example II, except that the package did not contain a wicking fabric in the space between the microporous barrier and the interior surface of the pouch. Instead, the hydrogel was placed in a syringe and injected between the microporous barrier and the interior surface of the pouch. In this example, the catheters did not include a no-touch sleeve. The packages were exposed to gamma radiation and stored, as described above in Example II. The initial, abraded and dry-out CoFs were measured and dye uptake tests were conduct in the same manner as described in Example II.

[0048] Table 7 lists the initial and abraded CoF measurements and the results of the dye test of the abraded catheter samples.

Table 7

Sample	Initial COF	Abrasion COF	Abraded Dye test
5-1	0.016	0.011	Pass
5-2	0.019	0.018	Pass
5-3	0.016	0.007	Pass
5-4	0.015	0.008	Pass
5-5	0.018	0.012	Pass
5-6	0.025	0.011	Pass
5-7	0.018	0.010	Pass
5-8	0.017	0.028	Pass
Average	0.018	0.013	
Std. Dev.	0.003	0.007	

[0049] Table 8 lists the dry out CoF measurements and the results of the dye test after the dry out CoFs were measured for the catheter samples.

Table 8

Sample	10Min Dry Out COF	Dried Dye test
5-9	0.018	Pass
5-10	0.022	Pass
5-11	0.027	Pass
5-12	0.030	Pass
5-13	0.029	Pass
5-14	0.027	Pass
5-15	0.026	Pass
5-16	0.031	Pass
Average	0.026	
Std. Dev.	0.004	

Example VI

[0050] A hydrogel including 1.5 wt% gellan gum, 0.1 wt% citric acid and 98.4 wt% water was formed in the manner described above in Example I. The catheters having a hydrophilic coating on the catheter shaft and a gas permeable no-touch sleeve surrounding the catheter shaft were individually packaged with the hydrogel in a vapor hydrating, gas impermeable package, as described above in Example IV (no wicking fabric). The packages were exposed to gamma radiation and stored, as described above in Example II. The initial, abraded and dry-out CoFs were measured and dye uptake tests were conduct in the same manner as described in Example II.

[0051] Table 9 lists the initial and abraded CoF measurements and the results of the dye test of the abraded catheter samples.

Table 9

Sample	Initial COF	Abrasion COF	Abraded Dye test
6-1	0.017	0.015	Pass

(continued)

Sample	Initial COF	Abrasion COF	Abraded Dye test
6-2	0.017	0.079	Pass
6-3	0.013	0.008	Pass
6-4	0.016	0.006	Pass
6-5	0.013	0.007	Pass
6-6	0.015	0.008	Pass
6-7	0.012	0.006	Pass
6-8	0.015	0.008	Pass
Average	0.015	0.017	
Std. Dev.	0.002	0.025	

[0052] Table 10 lists the dry out CoF measurements and the results of the dye test after the dry out CoFs were measured for the catheter samples.

Table 10

Sample	10Min Dry Out COF	Dried Dye test
6-9	0.023	Pass
6-10	0.025	Pass
6-11	0.025	Pass
6-12	0.028	Pass
6-13	0.025	Pass
6-14	0.024	Pass
6-15	0.026	Pass
6-16	0.023	Pass
Average	0.025	
Std. Dev.	0.002	

Example VII

[0053] A hydrogel including 1.5 wt% gellan gum, 0.1 wt% citric acid and 98.4 wt% water was formed in the manner described above in Example I. The catheters having a hydrophilic coating on the catheter shaft were individually packaged with the hydrogel in a vapor hydrating, gas impermeable package, as described above in Example IV (no wicking fabric). In this example, the catheter did not include a no-touch sleeve. The packages were exposed to gamma radiation and stored, as described above in Example II. The initial, abraded and dry-out CoFs were measured and dye uptake tests were conduct in the same manner as described in Example II.

[0054] Table 11 lists the initial and abraded CoF measurements and the results of the dye test of the abraded catheter samples.

Table 11

Sample	Initial COF	Abrasion COF	Abraded Dye test
7-1	0.015	0.006	Pass
7-2	0.013	0.008	Pass

(continued)

Sample	Initial COF	Abrasion COF	Abraded Dye test
7-3	0.018	0.015	Pass
7-4	0.014	0.085	Pass
7-5	0.019	0.016	Pass
7-6	0.019	0.008	Pass
7-7	0.014	0.013	Pass
7-8	0.017	0.027	Pass
Average	0.016	0.022	
Std. Dev.	0.003	0.026	

[0055] Table 12 lists the dry out CoF measurements and the results of the dye test after the dry out CoFs were measured for the catheter samples.

Table 12

Sample	10Min Dry Out COF	Dried Dye test
7-9	0.019	Pass
7-10	0.020	Pass
7-11	0.014	Pass
7-12	0.024	Pass
7-13	0.019	Pass
7-14	0.017	Pass
7-15	0.017	Pass
7-16	0.029	Pass
Average	0.020	
Std. Dev.	0.005	

Example VIII

[0056] A hydrogel including 1.375 wt% gellan gum, 0.375 wt% glycerol and 98.25 wt% was formed in the manner described above in Example I. The catheters having a hydrophilic coating on the catheter shaft and a no-touch sleeve covering the catheter shaft were individually packaged with the hydrogel in a gas impermeable foil package. In particular, the catheter and hydrogel were placed in the cavity of the gas impermeable foil package and the foil package was sealed. There was no barrier between the catheter and the hydrogel within the cavity.

[0057] The packages were then exposed to gamma radiation at a dose of between about 25 kGy and about 45 kGy. The packages were stored for five days. The initial, abraded and dry-out CoFs were measured and dye uptake tests were conducted in the same manner as described in Example II.

[0058] Table 13 lists the initial and abraded CoF measurements and the results of the dye test of the abraded catheter samples.

Table 13

Sample	Initial COF	Abrasion COF	Abraded Dye test
8-1	0.012	0.006	Pass

(continued)

Table 13			
Sample	Initial COF	Abrasion COF	Abraded Dye test
8-2	0.016	0.006	Pass
8-3	0.022	0.015	Pass
8-4	0.021	0.003	Pass
8-5	0.014	0.012	Pass
8-6	0.014	0.016	Pass
8-7	0.013	0.023	Pass
8-8	0.014	0.013	Pass
Average	0.016	0.012	
Std. Dev.	0.004	0.006	

[0059] Table 14 lists the dry out CoF measurements and the results of the dye test after the dry out CoFs were measured for the catheter samples.

Table 14		
Sample	10Min Dry Out COF	Dried Dye test
8-9	0.016	Pass
8-10	0.025	Pass
8-11	0.022	Pass
8-12	0.020	Pass
8-13	0.019	Pass
8-14	0.061	Pass
8-15	0.021	Pass
8-16	0.020	Pass
Average	0.025	
Std. Dev.	0.015	

Example IX

[0060] A hydrogel including 1.375 wt% gellan gum, 0.375 wt% glycerol and 98.25 wt% water was formed in the manner described above in Example I. The catheters having a hydrophilic coating on the catheter shaft were individually packaged with the hydrogel in a gas impermeable foil package. In particular, the catheter and hydrogel were placed in the cavity of the gas impermeable foil package and the foil package was sealed. There was no barrier between the catheter and the hydrogel within the cavity. Also, the catheter did not include a no-touch sleeve.

[0061] The packages were then exposed to gamma radiation at a dose of between about 25 kGy and about 45 kGy. The packages were stored for five days. The initial, abraded and dry-out CoFs were measured and dye uptake tests were conducted in the same manner as described in Example II.

[0062] Table 15 lists the initial and abraded CoF measurements and the results of the dye test of the abraded catheter samples.

Table 15			
Sample	Initial COF	Abrasion COF	Abraded Dye test
9-1	0.020	0.018	Pass
9-2	0.022	0.016	Pass
9-3	0.020	0.029	Pass
9-4	0.022	0.020	Pass
9-5	0.022	0.013	Pass
9-6	0.020	0.023	Pass
9-7	0.018	0.017	Pass
9-8	0.015	0.019	Pass
Average	0.020	0.019	
Std. Dev.	0.002	0.005	

[0063] Table 16 lists the dry out CoF measurements and the results of the dye test after the dry out CoFs were measured for the catheter samples.

Table 16		
Sample	10Min Dry Out COF	Dried Dye test
9-9	0.028	Pass
9-10	0.026	Pass
9-11	0.027	Pass
9-12	0.025	Pass
9-13	0.029	Pass
9-14	0.019	Pass
9-15	0.019	Pass
9-16	0.030	Pass
Average	0.025	
Std. Dev.	0.004	

Example X

[0064] In this example, a hydrogels were formed from the below listed compositions in the manner described in Example 1. Each of the hydrogels was individually placed in a pouch and the pouch was sealed. The pouches were then exposed to gamma radiation at a dose of about 25 kGy to about 40 kGy. After being exposed to radiation, the packages were opened and the consistency of the contents (hydrogel) was visual observed to determine if the gel transitioned into a liquid, remained a gel or was a semi-solid (partially a gel and some liquid). Any liquid within the package was then placed on both a white piece of fabric and a black piece of fabric. The fabric was allowed to dry and a visual inspection of the fabric was conducted to determine if any staining occurred.

[0065] Table 17 lists the results of this example.

Table 17							
Sample	Gellan Gum wt%	Glycerol wt%	Citric Acid wt%	Polyethylene Glycol wt%	Consistency of Contents	White Fabric	Black Fabric
10-1	2.0	0	0	0	Liquid	Yellow Stain	No Noticeable Stain
10-2	1.5	0	0	0	Liquid	Yellow Stain	No Noticeable Stain
10-3	1.5	0.5	0	0	Liquid	No Noticeable Stain	Fragments of White Deposit
10-4	1.25	0	0	0	Liquid	Yellow Stain	No Noticeable Stain
10-5	1.25	0.5	0	0	Liquid	No Noticeable Stain	No Noticeable Stain
10-6	1.25	1	0	0	Liquid	Fragments of White Deposit	Transparent Film Formed
10-7	1.25	0.5	0.05		Liquid	No Noticeable Stain	Transparent Film Formed
10-8	1.25	0.5	0.1		Semi-solid	Transparent Film Formed	Transparent Film Formed
10-9	1	0	0	0	Liquid	Yellow Stain	No Noticeable Stain
10-10	1	0.5	0	0	Liquid	No Noticeable Stain	No Noticeable Stain
10-11	1	1	0	0	Semi-solid	No Noticeable Stain	Fragments of White Deposit
10-12	1	0	0	0.5	Liquid	Fragments of White Deposit	Transparent Film Formed
10-13	1	0	0	1.0	Liquid	Fragments of White Deposit	Transparent Film Formed

[0066] It will be understood that the embodiments described above are illustrative of some of the applications of the principles of the present subject matter. Numerous modifications may be made by those skilled in the art without departing from the spirit and scope of the claimed subject matter, including those combinations of features that are individually disclosed or claimed herein. For these reasons, the scope hereof is not limited to the above description but is as set forth in the following claims, and it is understood that claims may be directed to the features hereof, including as combinations of features that are individually disclosed or claimed herein.

[0067] Various additional features of the invention are set out hereinafter.

1. An assembly, comprising:

   a device; and
   a radiation activated fluid releasing gel containing a fluid.

2. The assembly of feature 1 wherein the gel is configured to release the fluid upon exposure to radiation.
3. The assembly of any one of features 1-2 wherein the fluid comprises water.
4. The assembly of any one of features 1-3 wherein the fluid comprises an additive.
5. The assembly of any one of features 1-4 wherein the gel comprises a hydrogel.
6. The assembly of any one of features 1-5 wherein the gel comprises a polysaccharide based gel.
7. The assembly of any one of features 1-6 wherein the gel comprises gellan gum.
8. The assembly of any one of features 1-7 wherein the gel degrades upon exposure to radiation, thereby releasing

the fluid.

9. The assembly of any one of features 1-8 wherein the device comprises a medical device.

10. The assembly of any one of features 1-9 wherein the device comprises a urinary or anal catheter.

11. The assembly of feature 10 wherein the catheter is a urinary catheter includes a shaft and at least the catheter shaft is surrounded by a sleeve, and the catheter shaft and gel are contained within the sleeve.

12. The assembly of any one of features 1-11 further comprising a package wherein the device and gel are located within the package.

13. The assembly of any one of features 1-12 wherein the device comprises a hydrophilic material.

14. The assembly feature 13 wherein the hydrophilic material comprises a hydrophilic coating.

15. The assembly of any one of features 1-14 wherein the gel is in contact with the device.

16. The assembly of any one of features 1-15 wherein the gel at least partially covers the device.

17. The assembly of any one of features 1-15 wherein the gel is separated from the device.

18. The assembly of feature 17 wherein a gas permeable barrier separates the gel from the device.

19. The assembly of any one of features 17 and 18 wherein the fluid released from the gel donates a vapor that contacts the device.

20. The assembly of any one of features 1-10 wherein the gel and device are unconfined within a package.

21. The assembly of any one of feature 1-19 wherein the gel and device are within a package and the gel is contained within a section of the package.

22. The assembly of any one of features 1-21 wherein a concentration of the fluid in the gel comprises about 40 wt% and 99.8 wt%.

23. The assembly of any one of features 1-22 wherein a concentration of the fluid in the gel comprises 98 wt%.

24. The assembly of any one of features 1-23 wherein the gel comprises an anti-staining additive.

25. The assembly of feature 24 wherein the anti-staining additive comprises one or more of glycerol, polyethylene glycol and citric acid.

26. The assembly of any one of features 1-25 wherein the gel comprises a stabilizing agent.

27. The assembly of feature 26 wherein the stabilizing agent comprises one or more of glycerol, polyethylene glycol and citric acid.

28. A method of sterilizing a device, comprising:

placing a device and a gel containing a fluid within a package; and
exposing the device and gel to sterilizing radiation, wherein the gel is activated to release the fluid upon exposed to the radiation.

29. The method of feature 28 wherein the fluid comprises water.

30. The method of any one of features 28-29 wherein the fluid comprises an additive.

31. The method of any one of features 28-30 wherein the gel comprises a hydrogel.

32. The method of any one of features 28-31 wherein the gel comprises a polysaccharide based gel.

33. The method of any one of features 28-32 wherein the gel comprises gellan gum.

34. The method of any one of features 28-33 wherein the gel degrades upon exposure to radiation, thereby releasing the fluid.

35. The method of any one of features 28-34 wherein the device comprises a medical device.

36. The method of feature 35 wherein the medical device comprises a urinary or anal catheter.

37. The method of any one of features 28-36 wherein the device comprises a hydrophilic material.

38. The method of feature 37 wherein the hydrophilic material comprises a hydrophilic coating.

39. The method of any one of features 28-38 wherein the gel is in contact with the device.

40. The method of feature 39 wherein the gel at least partially covers the device.

41. The method of any one of features 28-38 wherein the gel is separated from the device.

42. The method of feature 41 wherein a gas permeable barrier separates the gel from the device.

43. The method of any one of features 41 - 42 wherein the fluid released from the gel donates a vapor that contacts the device.

44. The method of any one of features 28-40 wherein the gel and medical device are unconfined within a package.

45. The method of any one of features 28-38 wherein the gel and medical device are within a package and the gel is contained within a section of the package.

46. The method of feature 36 wherein the catheter is a urinary catheter that includes a catheter shaft and at least the catheter shaft is surrounded by a sleeve and the catheter shaft and gel are contained within the sleeve.

47. The method of feature 36 wherein the catheter is a urinary catheter that includes a catheter shaft at least the catheter shaft is surrounded by a sleeve and the gel is located outside of the sleeve.

48. The method of any one of features 28-47 wherein a concentration of the fluid in the gel comprises about 40 wt%

and 99.8 wt%.

49. The method of any one of features 28-47 wherein a concentration of the fluid in the gel comprises about 98 wt%.
50. The method of any one of features 28-49 wherein the gel comprises an anti-staining additive.
51. The method of feature 50 wherein the anti-staining additive comprises one or more of glycerol, polyethylene glycol and citric acid.
52. The method of any one of features 28-51 wherein the gel comprises a stabilizing agent.
53. The method of feature 52 wherein the stabilizing agent comprises one or more of glycerol, polyethylene glycol and citric acid.

Claims

1. An assembly, comprising:

a package including a urinary or anal catheter comprising a hydrophilic material; and
a radiation activated fluid releasing gel containing a fluid configured to release fluid upon exposure to radiation.

2. The assembly of claim 1, wherein the fluid comprises water, and preferably water and an additive.

3. The assembly of any one of claims 1-2 wherein the gel comprises a hydrogel.

4. The assembly of any one of claims 1-3 wherein the gel comprises a polysaccharide based gel.

5. The assembly of any one of claims 1-4 wherein the gel comprises gellan gum.

6. The assembly of any of claims 1-5 wherein the catheter is the urinary catheter includes a shaft and at least the catheter shaft is surrounded by a sleeve, and the catheter shaft and gel are contained within the sleeve.

7. The assembly claim 1 wherein the hydrophilic material comprises a hydrophilic coating.

8. The assembly of any one of claims 1-7 wherein the gel is in contact with the urinary or anal catheter.

9. The assembly of any one of claims 1-8 wherein the gel at least partially covers the urinary or anal catheter.

10. The assembly of any one of claims 1-7 wherein the gel is separated from the urinary or anal catheter.

11. The assembly of claim 10 wherein a gas permeable barrier separates the gel from the urinary or anal catheter.

12. The assembly of any one of claims 10 and 11 wherein the fluid released from the gel donates a vapor that contacts the urinary or anal catheter.

13. The assembly of any one of claim 1-12 wherein the gel and urinary or anal catheter are within a package and the gel is contained within a section of the package.

14. The assembly of any one of claims 1-13 wherein a concentration of the fluid in the gel comprises about 40 wt% and 99.8 wt%, preferably the concentration of the fluid is 98 wt%.

15. The assembly of any one of claims 1-14 wherein the gel comprises an anti-staining additive, preferably glycerol, polyethylene glycol and citric acid.

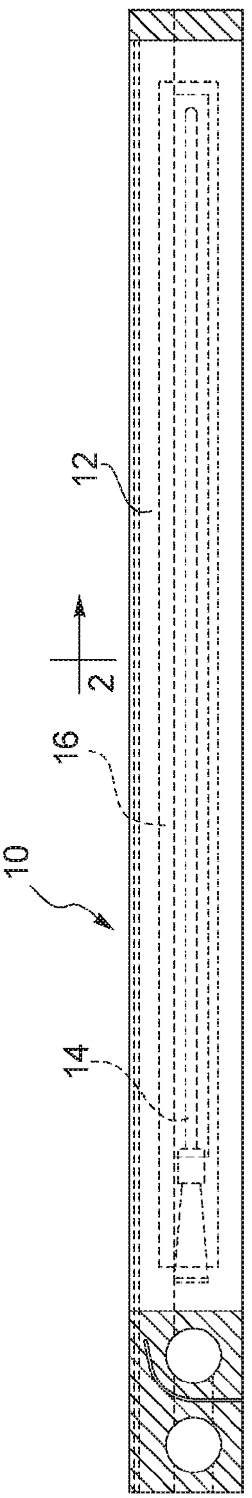

FIG. 1

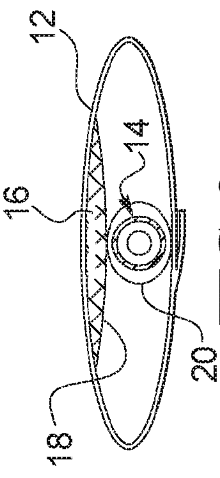

FIG. 2a

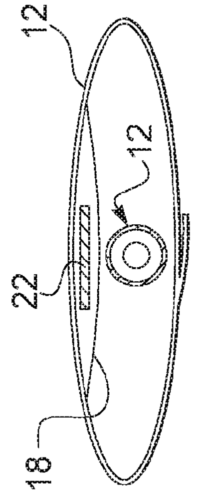

FIG. 2b

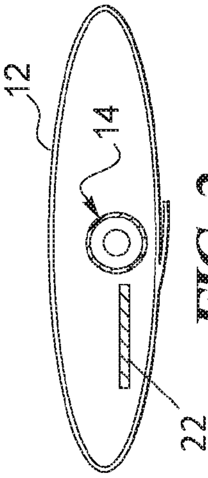

FIG. 2c

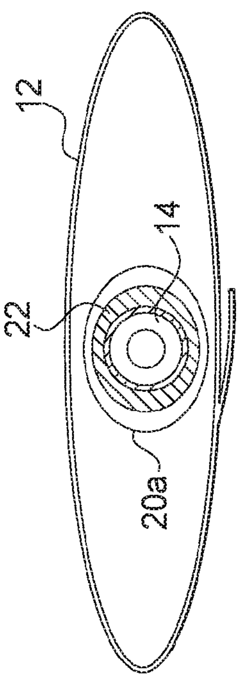

FIG. 2d

REFERENCES CITED IN THE DESCRIPTION

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- US 62461730 **[0001]**
- US 62545730 **[0001]**